DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

ARTHREX, Incorporated
Ms. Laura Medlin
Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, Florida 34108-1945

November 19, 2014

Re: K143047
Trade/Device Name: Arthrex iBalance Patella Implant, Dome
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: October 20, 2014
Received: October 23, 2014

Dear Ms. Medlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143047

Device Name
Arthrex iBalance Patella Implant, Dome

Indications for Use *(Describe)*
The Arthrex iBalance TKA System is indicated for use in individuals undergoing surgery for:

- Painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis;
- Post-traumatic loss of knee joint configuration and function;
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability;
- Revisions of previous unsuccessful knee replacement or other procedure.

Additional indications for posteriorily stabilized components:

- Ligamentous instability requiring implant bearing surfaces with increased constraint;
- Absent or non-functioning posterior cruciate ligament.

These devices are single use only and are intended for implantation with bone cement.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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2.6 510K SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared	October 20, 2014
Manufacturer/ Distributor/ Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Laura Medlin Regulatory Affairs Associate Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext.72005 Fax: 239/598.5508 Email: Laura.Medlin@Arthrex.com
Trade Name	***Arthrex iBalance Patella Implant, Dome***
Common Name	Knee Prosthesis
Product Code, Classification Name, CFR	**JWH** 21 CFR 888.3560: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
Predicate Device	K133854: *Arthrex iBalance TKA System, Patella Implant, Dome* K081127: *Accin Total Knee System*
Purpose of Submission	This special 510(k) premarket notification is submitted to obtain clearance for a line extension to the current patella dome devices of the *Arthrex iBalance Total Knee System*.
Device Description	The *Arthrex iBalance Total Knee System* consists of femoral devices, tibial trays, tibial bearing and patellar devices. All devices are available in a range of sizes to fit varying anatomical requirements. Femoral devices and tibial bearing devices are available in both posteriorly stabilized (PS) and cruciate retaining (CR) configurations. Femoral devices are available in left and right versions and are designed to work with the Arthrex dome patella devices. Femoral and tibial tray devices are manufactured from Cobalt Chromium Alloy conforming to ASTM F75. Tibial bearing and patellar devices are manufactured from UHMWPE conforming to ASTM F648. The ***Arthrex iBalance Patella Implant, Dome*** subject of this application is comparable to the system's current dome patella devices with the exception that the proposed device will be offered in a larger size to further compliment the *Arthrex iBalance Total Knee System* product offering.
Intended Use	The *Arthrex iBalance TKA System* is indicated for use in individuals undergoing surgery for: • Painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis; • Post-traumatic loss of knee joint configuration and function; • Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability; • Revisions of previous unsuccessful knee replacement or other procedure. Additional indications for posteriorly stabilized components: • Ligamentous instability requiring implant bearing surfaces with increased constraint; Absent or non-functioning posterior cruciate ligament. These devices are single use only and are intended for implantation with bone cement.
Substantial Equivalence Summary	The ***Arthrex iBalance Patella Implant, Dome*** is substantially equivalent to the predicate devices in which the basic design features and intended uses are the same. Any differences between the ***Arthrex iBalance Patella Implant, Dome*** and the predicates are considered minor and do not raise questions concerning safety

	and effectiveness. The predicate *Arthrex iBalance TKA System* is a total knee arthroplasty system consisting of femoral devices, tibial trays, tibial bearing and patellar devices. This application serves to introduce one (1) new size of the patella dome device. No additional changes have been made to the previously cleared devices of the *Arthrex iBalance TKA System* as a result of this application. The subject ***Arthrex iBalance Patella Implant, Dome*** is equivalent to the currently available predicate Patella Implant, Domes (K133854) in which the basic features and intended uses are the same. Any differences between the ***Arthrex iBalance Patella Implant, Dome*** and the predicates are considered minor and do not raise questions concerning safety and effectiveness. The proposed patella dome device is substantially equivalent to the predicate devices in regards to its intended use, design, size range, and material. An evaluation of the geometries and design features of the predicate and subject devices demonstrated that the proposed device provides adequate stability to support the use of the ***Arthrex iBalance Patella Implant, Dome*** for the referenced indications. Based on the indication for use, technological characteristics, and the comparison to the predicate device, Arthrex, Inc. has determined that the ***Arthrex iBalance Patella Implant, Dome*** is substantially equivalent to currently marketed predicate devices.